Real-world performance of an enhanced atrial fibrillation detection algorithm in an insertable cardiac monitor

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BACKGROUND Insertable cardiac monitors (ICMs) are used for long-term ECG monitoring. The Reveal LINQ ICM has an improved atrial fibrillation (AF) detection algorithm.

OBJECTIVE The purpose of this study was to investigate the algorithm's real-world performance in patients with syncope, cryptogenic stroke, and known AF.

METHODS Consecutive patients with implanted ICM and AF detection parameters automatically set and maintained depending on the indication for monitoring were included. A single reviewer annotated all stored episodes after ICM implant. A second reviewer annotated a random sample of 10% of all detected AF episodes. The episode detection positive predictive value as well as true and false detection rates were determined for AF episodes of different durations.

RESULTS The study enrolled 3759 patients (1604 [43%] with syncope, 1049 [28%] with known AF, 1106 [29%] with cryptogenic stroke). Overall, 20,659 AF episodes were detected in 1020 patients. The gross episode detection positive predictive value was 84%, 73%, and 26% for all episodes (≥2 minutes) and improved to 97%, 95%, and 91% for detected AF episodes ≥1 hour in the syncope, known-AF, and cryptogenic stroke patient cohorts, respectively. The true (and false) detection rate was 0.23 (0.05), 3.8 (1.4), and 0.23 (0.65) per patient-month of monitoring for the syncope, known-AF, and cryptogenic stroke patient cohorts, respectively. Limiting ECG storage to the longest detected AF episode significantly reduced the burden of episode adjudication without significantly compromising the identification of patients with true AF.

CONCLUSION The performance of LINQ ICM is dependent on the AF incidence rate in the population being monitored, the programmed sensitivity of AF algorithm, and the duration of detected AF episodes.

KEYWORDS Atrial fibrillation; Insertable cardiac monitor; Diagnosis and monitoring

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Introduction

Subcutaneous insertable cardiac monitors (ICMs) use incoherence of R-R intervals over a period of time to detect atrial fibrillation (AF).[1] Although not as accurate as implantable devices that incorporate a sensing lead in the right atrium,[2] ICMs still have been shown to have high accuracy in detecting AF.[1,3] Continuous long-term ECG monitoring provided by ICMs improves the ability to diagnose the presence or absence of AF compared with intermittent ECG monitoring tools such as Holter monitoring[4,5] or reliance on patient symptoms alone.[6] ICMs have been used for diagnosing and monitoring of recurrent AF after surgical and catheter ablation of AF,[5,7–9] catheter ablation of atrial flutter,[10] and in patients with history of cryptogenic stroke.[11,12] However, a perceived high rate of inappropriate AF detection, especially in patients with low incidence of AF, has been considered an impediment for routine use of ICMs.[9] Yet, these are the patients who are most likely to benefit from continuous and long-term ECG recordings compared with short-term external ECG monitoring.

To date, much of the diagnostic utility of ICMs has been derived from studies using the Reveal XT (Medtronic, Minneapolis, MN) ICM. Recently, a second-generation ICM (Reveal LINQ, Medtronic) has become commercially available. This device was developed with a better electrode coating and novel implant technique to improve the quality of the recorded ECG signal. In addition, the device features an improved AF detection algorithm based on the recognition of a single P wave between 2 R waves using morphologic processing of the ECG signal. When evaluated against the original device algorithm using 48-hour Holter recordings in a population with known paroxysmal AF, the new algorithm was shown to improve specificity and positive

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predictive value (PPV) for AF detection while preserving sensitivity.[13] The main objective of this study was to evaluate the real-world AF episode detection performance in the LINQ ICM over follow-up in a large cohort of patients undergoing ECG monitoring for various indications.

Methods

Study cohort

All consecutive patients implanted with a Reveal LINQ ICM device with at least 3 months of follow-up postimplant were selected from the de-identified Medtronic Discovery Link database. All patients provided consent to use their device data for research purposes. In this study, we included patients with unexplained syncope, cryptogenic stroke, and known AF who underwent LINQ implantation for long-term ECG monitoring. Table 1 lists the automatically programmed AF detection settings for the different indications for ICM implant, which is based on the expected incidence rate of AF and the clinical relevance of AF detection in the patient population. (We excluded all patients not programmed according to the recommended AF detection settings.) Programming was optimized to maintain high specificity (accepting somewhat lower sensitivity) in patients with unexplained syncope. In contrast, in patients with cryptogenic stroke, programming was guided by the need to maintain as high sensitivity as possible, even for very short duration episodes of AF (thus accepting somewhat lower specificity).

AF detection algorithm

In an ICM, AF detection is based on incoherence of R-R intervals.[1] This algorithm was prospectively evaluated in the XPECT study using Reveal XT devices.[3] The R-R interval–based algorithm was recently enhanced by incorporating P-wave evidence information in Reveal LINQ devices.[13] The P-wave evidence mode (off, nominal, and aggressive) and the detection threshold (more sensitive, balanced sensitivity, less sensitive, and least sensitive) are programmable parameters, which can be used to tailor the detection sensitivity and specificity of the AF algorithm to the clinical indication for ECG monitoring (Table 1).[13]

The AF detection algorithm makes a decision every 2 minutes. If an episode is detected as AF, the first 2 minutes of ECG from that episode can be stored in the device. The device can store up to 14 AF episodes with an ECG, after which the most recent AF episode overwrites the earliest AF episode. ECG data from the longest detected AF episode (≥10 minutes) since the last full manual transmission is always preserved in memory. After the next full manual transmission, the device will restart, looking for the new longest episode. The patient can manually transmit full information on all stored episodes at any time. Additionally, every night the Reveal LINQ device automatically and wirelessly transmits the last 10 seconds of the 2-minute ECG segment from the longest episode (at least ≥10 minutes or per duration-based episode storage programming described later) of AF observed during that day and stored in device memory.

The device can store ECG information on all detected episodes of AF (by design, these episodes must be ≥2 minutes), as described earlier. However, the device also provides additional programmable options to preserve ECG storage memory. Specifically, the clinician can program the device to store ECG only for AF episodes ≥6 minutes, ≥10 minutes, ≥ 30minutes, or ≥60 minutes. A final option allows one to restrict ECG storage to only the longest AF episode; however, the longest AF episode must be ≥10 minutes.

Thus, if one chooses to store ECG only for episodes ≥10 minutes, the device will only log and store ECG information for up to the last 14 episodes that have duration ≥10 minutes, in addition to the longest AF episode. The device will still detect episodes (but not log or store the ECG) of shorter durations (<10 minutes) and add them to cumulative total duration of detected AF (AF burden). If one chooses to only store the longest AF episode, then at any given time only 1 episode (≥10 minutes) is stored in device memory. Only the longest episode stays in device memory until a new episode that is longer in duration is detected by the device or the episode in memory is transmitted by a full manual download of the device.

Episode annotation

All episodes collected by the device during the first 3 months after implant that were stored with either a 10-second or a 2-minute ECG segment were reviewed by a single reviewer (SS). A random sampling of 10% of episodes was re-reviewed by the same reviewer to determine intrareviewer variability. Another 10% random sample was reviewed by a

Table 1 Nominal atrial fibrillation detection programming based on the indication for insertable cardiac monitor implant

	Indication for ICM implant		
AF detection programming in ICM	Syncope	Known AF	Cryptogenic stroke
AF detection type	AF only*	AF only*	AF only*
AF detection sensitivity	Least sensitive*	Balanced sensitivity*	Balanced sensitivity*
Ectopy rejection	Aggressive*	Nominal*	Aggressive*
ECG storage	Longest episode only†	All episodes†	All episodes†

AF = atrial fibrillation; ICM = insertable cardiac monitor.

*All patients had to be programmed in this mode for inclusion in data cohort.

†Not all patients had to be programmed in this mode for inclusion in data cohort.

second reviewer (TTT; senior electrophysiology fellow) who was blinded to the patient's indication for ICM implantation. Any discordance between the first and second reviewers was adjudicated by a third reviewer (RSP; board-certified electrophysiology attending) to ascertain the inter-reviewer variability. Episodes were considered to be true if there was a ≥10-second ECG segment showing an atrial tachycardia or AF.

Statistical analysis

AF episode detection PPV was computed as the ratio of the total number of AF episodes in all patients that were annotated to be true and the total number of AF episodes that were detected by the device and stored with an ECG in all patients. Patient average episode detection PPV, which averages the effect of multiple episodes in patients, was evaluated by computing the episode detection PPV for each patient and then averaging across all patients. Episode detection sensitivity cannot be computed in this dataset because there is no knowledge about true AF episodes that were not detected by the device (i.e., false-negative episodes are not recorded in this dataset). Episode detection specificity and negative predictive value cannot be defined because a true negative episode cannot be defined in this dataset. True and false episode detection rates were computed as the total number of appropriate and inappropriate detections per month during the entire follow-up duration of 3 months for each patient. True and false detection rates for each patient were then averaged across all patients to estimate the mean true and false detection rates. Episode detection PPV and true and false detection rates are separately reported for the 3 patient populations: patients with unexplained syncope, cryptogenic stroke, or known AF. Within each patient population, the performance metrics were determined as a function of the duration of detected episode.

Results

The study enrolled 3759 patients, including 1604 (43%) with unexplained syncope, 1106 (29%) with cryptogenic stroke, and 1049 (28%) with known AF (Table 2). In the first 3 months postimplant, the ICMs recorded a total of 20,659 AF episodes. Not surprisingly, AF was most commonly recorded in patients with known AF. These patients accounted for 16,506 (80%) of all recorded AF episodes.

The first reviewer re-reviewed a random sample containing 10% of all detected events. In >99% of instances, the initial and second reviews classified the events similarly. A second reviewer reviewed a random sample of 2230 episodes. Overall, 2216 of these events (99.4%) were classified similar to the first reviewer.

AF episode detection performance during long-term follow-up is given in Table 2. For all detected episodes with an associated stored ECG available for review, the raw (and average of per-patient) episode detection PPV, or the proportion of all reviewed episodes that was true atrial tachycardia or AF, was 84% (80%), 73% (73%), and 26% (33%) for the syncope, known-AF, and cryptogenic stroke patient cohorts, respectively.

The rate of detection of true episodes of AF was much higher in the known-AF patient cohort (3.8 episodes per patient-month) compared to the syncope and cryptogenic stroke patient cohorts; both of these cohorts had 0.23 true AF episodes per patient-month of monitoring. The rate of detection of false AF episodes was also highest in the known-AF patient cohort (1.4 episodes per patient-month). The rate was lower in the cryptogenic stroke patient cohort (0.65 episodes per patient-month) and lowest in the syncope patient cohort (0.05 episodes per patient-month). Thus, if an implanting center had 100 patients with an ICM for each of the 3 indications, one could expect to receive 520, 88, and 28 detected (true + false) AF episodes (with an available stored ECG) each month in the known-AF, cryptogenic stroke, and syncope patient cohorts, respectively. Of these detections, 140 (27%), 65 (74%), and 5 (18%) episodes in each of the respective cohorts would be for an inappropriate detection of AF.

The true- and false-positive AF detection rates are a function of the relative incidence rates of AF in these patient cohorts as well as the programmed settings for AF detection (Table 1). Of note, although the cryptogenic stroke patient cohort has a lower PPV (26%) compared to the known-AF patient cohort (73%), the absolute rate of inappropriate AF detections is much lower in the cryptogenic stroke patient

Table 2 Long-term episode detection performance for different patient cohorts for all detected atrial fibrillation episodes

	Syncope	Known AF	Cryptogenic stroke
No. of patients	1604	1049	1106
Age (years)	63 ± 19	66 ± 11	65 ± 14
Male gender (%)	44	63	52
No. of detected AF episodes	1346	16,506	2807
No. with a true AF episode	1124 (84%)	11,974 (73%)	720 (26%)
Patients with a detected AF episode	192 (12%)	605 (58%)	223 (20%)
Patients with true AF episodes	156 (81%)	494 (82%)	87 (39%)
True-positive rate (per patient-month)	0.23	3.8	0.23
False-positive rate (per patient-month)	0.05	1.4	0.65
Positive predictive value (raw)	84%	73%	26%
Positive predictive value (patient average)	80%	73%	33%

AF = atrial fibrillation.

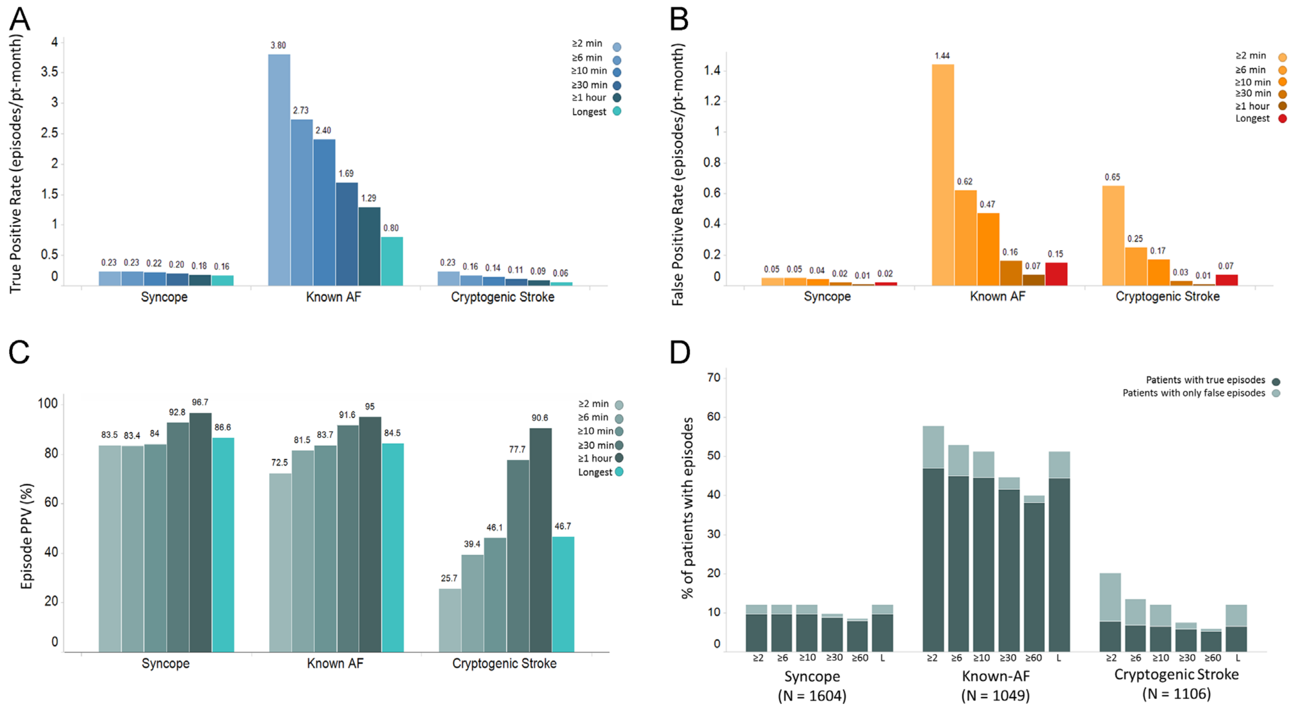

Figure 1 Long-term atrial fibrillation (AF) episode detection performance as a function of detected AF episode duration and stratified by patient cohort. **A:** True-positive episode detection rate. **B:** False-positive episode detection rate. **C:** Raw positive predictive value for episode detection. The longest episode storage setting keeps in memory only the longest AF detected episode that is ≥10 minutes since the last full manual transmissions. **D:** Episode detection yield represented as percentage of patients with detected and true episodes for the different episode detection settings.

cohort (0.65 per patient-month) compared to the known-AF patient cohort (1.4 per patient month). The lower PPV in the cryptogenic patient cohort is primarily driven by the lower incidence rate of AF.

The true-positive and false-positive episode AF detection rate as well as the raw PPV of episode detection as a function of detected episode duration are shown in Figures 1A, 1B, and 1C, respectively. The true- and false-positive detection rate reduces as a function of the detected episode duration. Net reclassification indices as a function of episode duration are presented in the Online Supplemental Appendix. The episode detection PPV improves with increased detected episode duration, with 97%, 95%, and 91% of detected AF episodes ≥1 hour in duration being true in the syncope, known-AF, and cryptogenic stroke cohorts, respectively.

The episode detection yield as a function of the programmed episode duration for detection is given in Table 3. For example, in the known-AF patient cohort, choosing to review only AF episodes ≥10 minutes or only the longest episode reduces the number of episodes needing review from 16,506 to 9030 (relative reduction of 45%) or 2990 (relative reduction of 82%), respectively (Table 3 and Figure 1D). If the ≥10-minute approach was adopted, true AF would be missed in only 26 (relative reduction of 5%) of 494 patients with an additional loss of 2 patients if the longest episode was chosen. However, in these patients, *all* detected AF episodes were <10 minutes in duration (2.4 episodes per patient with mean duration of 2.9 minutes per episode). Furthermore, it should be acknowledged that in a small cohort of patients, there would be a slight delay in diagnosis of AF. Of the 468 patients in whom at least 1 episode of AF ≥10 minutes was detected, 101 patients (20%) had an initial AF episode that was <10 minutes. These patients subsequently had a longer episode in a median of 10 hours (interquartile range 0.5–187 hours).

Similarly, in the cryptogenic stroke patient cohort, choosing to only review AF episodes ≥10 minutes or the longest episode reduces the number of episodes needing review from 2807 to 990 (relative reduction of 65%) or 418 (relative reduction of 85%), respectively (Table 3 and Figure 1D). If either approach was adopted, true AF would be missed in 14 (relative reduction of 16%) of 87 patients (with no additional loss going to the longest episode) with true episodes of AF; however, in these patients, *all* detected AF episodes were <10 minutes in duration (2.4 episodes per patient with mean duration of 2.9 minutes per episode). Furthermore, in a small cohort of patients, there would be slight delay in diagnosis of AF. Of the 73 patients in whom at least 1 episode of AF ≥10 minutes was detected, 7 patients (8%) had an initial AF episode that was <10 minutes. These patients subsequently had a longer episode in a median of 280 hours (interquartile range 10-492 hours). Figure 2 shows the Kaplan–Meier estimates for true AF detection rates illustrating the loss and delay in diagnostic yield in the cryptogenic stroke patient cohort.

Inappropriate episode detection was caused by various physiologic (e.g., runs of ectopy with irregular coupling, sick sinus, sinus tachycardia) and nonphysiologic reasons (e.g., oversensing or undersensing). In the syncope, known-AF, and cryptogenic stroke patient cohorts, 100%, 94%, and 97%

Table 3 Episode detection yield for different patient cohorts as a function of duration of detected atrial fibrillation episode over 3-month postimplant follow-up period

Indication for ICM implant	Detected episode duration groups	No. of episodes	No. of true episodes (PPV)	No. of patients with episodes (%)	No. of patients with true episodes (%)
Syncope (N = 1604 patients)	All	1346	1124 (84%)	192 (12%)	156 (81%)
	≥6 min	1336	1114 (83%)	192 (12%)	156 (81%)
	≥10 min	1288	1082 (84%)	192 (12%)	156 (81%)
	≥30 min	1029	955 (93%)	155 (10%)	141 (91%)
	≥1 hour	873	844 (97%)	134 (8%)	128 (96%)
	Longest	865	749 (87%)	192 (12%)	156 (81%)
Known AF (AF ablation/ management) (N = 1049 patients)	All	16,506	11,974 (73%)	605 (58%)	494 (82%)
	≥6 min	10,555	8601 (81%)	555 (53%)	473 (85%)
	≥10 min	9030	7555 (84%)	537 (51%)	468 (87%)
	≥30 min	5801	5313 (92%)	468 (45%)	436 (93%)
	≥1 hour	4277	4063 (95%)	419 (40%)	401 (96%)
	Longest	2990	2527 (85%)	537 (51%)	466 (87%)
Cryptogenic stroke (N = 1106 patients)	All	2807	720 (26%)	223 (20%)	87 (39%)
	≥6 min	1308	515 (39%)	148 (13%)	75 (51%)
	≥10 min	990	456 (46%)	132 (12%)	73 (55%)
	≥30 min	452	351 (78%)	82 (7%)	64 (78%)
	≥1 hour	318	288 (91%)	65 (6%)	59 (91%)
	Longest	418	195 (47%)	132 (12%)	73 (55%)

AF = atrial fibrillation; ICM = insertable cardiac monitor; PPV = positive predictive value.

of inappropriate detections, respectively, were primarily due to physiologic reasons.

Discussion

There are several important findings of this study, which evaluated the real-world performance of the LINQ ICM with an enhanced AF detection algorithm in 3 distinct patient cohorts. First, the episode PPV for any detected AF episode of ≥1-hour duration is >90%, irrespective of indication for long-term ECG monitoring. Second, for short-duration episodes of AF, the episode detection performance is dependent on the incidence rate of AF in the patient population being monitored and the duration of each detected AF episode. The performance is most problematic in cohorts such as those with cryptogenic stroke in which the incidence rate of AF is low yet the device by design is programmed to favor very high sensitivity for AF detection. Third, in patients with known AF, despite the high episode PPV, the high incidence rate of AF generates a high volume of detected AF episodes that require adjudication. Finally, the LINQ ICM offers the opportunity to limit ECG storage to the longest detected AF episode. Incorporation of this programming option can significantly reduce the burden of AF episode adjudication without significantly compromising the identification of patients with true AF, particularly in clinical situations in which identification of short-duration episodes may not be clinically relevant.

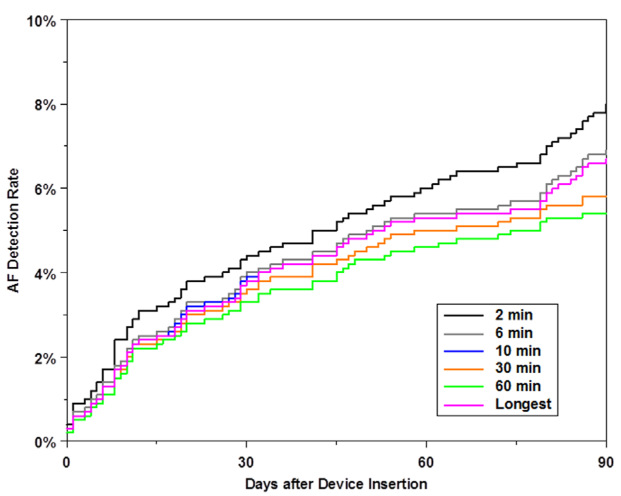

Figure 2 Kaplan–Meier estimates for true atrial fibrillation (AF) detection rates illustrate the loss and delay in diagnostic yield in the cryptogenic stroke patient cohort.

ICMs are increasingly being used for long-term ECG monitoring in patients with suspected or known history of AF.[7–10] In these patients, the goal of the AF detection algorithm not only is identify which patients are having AF but also to quantify accurately the type and amount of AF and the average ventricular rate during the entire duration of AF such that appropriate clinical management decisions can be taken in a timely manner. Although there is no consensus regarding clinically relevant duration of AF, several studies have shown an association between the amount of AF and increased risk of stroke[14,15] and risk for heart failure events,[16] suggesting that the amount of AF is clinically relevant.

The episode detection PPV improves with duration of detected episode. The basic reason is that causes of false AF detection, such as runs of ectopy with irregular coupling, are sporadic in nature and do not persist over a long time in contrast to true AF. Hence, longer episodes are more likely to be true AF episodes. The clinical burden inherent to the need to adjudicate episodes of AF has been a limitation to the routine use of ICMs for diagnosis of AF in all patient cohorts. One way to reduce episode review burden is to review only longer AF episodes.

The Reveal ICM is being used to diagnose AF in patients with cryptogenic stroke.[11,12] The goal is to identify patients who have AF and initiate anticoagulation treatment to prevent a secondary stroke. Additionally, by limiting anticoagulation to patients with documented AF, patients without an indication for anticoagulation are spared the risk of bleeding inherent to these medications. By design, the ICM is programmed to favor high sensitivity in these patients. However, given the low incidence rate of AF in these patients, the result is low episode detection PPV. On the other hand, in patients with known AF, a very high number of AF episodes is detected. In both clinical scenarios, a great deal of time and effort is needed to adjudicate the stored electrograms.

We suggest a new programming strategy in patients being implanted with a LINQ ICM in whom therapeutic decisions will not be altered based on short episodes of AF (<10 minutes). Instead of storing the ECG for all detected AF episodes, ECG storage is limited to the longest episode of AF. By design, when this programming option is chosen, the device stores the ECG for the longest AF episode lasting ≥ 10 minutes. This significantly reduces the number of AF episodes that require adjudication, with only a small loss in diagnostic yield. However, it is important to recognize that the small number of patients in whom *all* AF episodes are <10 minutes will be "missed" by this approach. In some patients, there may be a slight delay in the diagnosis of AF; however, whether this delay adversely impacts clinical outcomes remains unclear. At any time, a manual transmission can be requested to "reset" the longest AF duration counter. This is useful when (1) an intervention is made (e.g., antiarrhythmic drug initiated, catheter ablation performed, anticoagulation stopped) and (2) review of the longest AF episode shows it to be a false detection *and* identification of a true episode of that duration would alter clinical management.

Our data show that when AF episodes last ≥ 1 hour, PPV increases to 95%. This long duration cutoff may be entirely acceptable in a cohort of patients with known AF, as shorter duration episodes may not impact clinical decision-making. Two recent studies have investigated whether patients with known AF can be managed by using the ICM to determine if they are or are not having AF episodes ≥ 1 hour. Zuern et al[17] investigated 65 patients with a $CHADS_2$ score between 1 and 3 who remained free of AF 3 months after catheter ablation. An ICM was implanted and interrogated daily to determine whether there was ≥ 1-hour AF. Anticoagulation was initiated only if AF ≥ 1 hour was detected. During follow-up of 32 ± 12 months, anticoagulation was withheld in 41 patients (63%); no stroke, transient ischemic attack, or other thromboembolic event was observed. Passman et al[18] investigated 59 patients with nonpermanent AF and $CHADS_2$ score of 1 or 2. After ICM implantation, anticoagulation was withdrawn if no episodes of AF ≥ 1 hour were observed in the first 60 days. If an AF episode ≥ 1 hour was detected by the ICM, anticoagulation was reinitiated for 30 days and then stopped as long as no additional episodes of AF occurred. This "pill-in-the-pocket" method of anticoagulation reduced the cohort's exposure to an anticoagulant by 94%; no strokes or deaths were observed in this pilot study.

Study limitations

The main limitation of the study is that episode detection sensitivity cannot be ascertained because information about occurrences of underdetected AF is not available with the current design of the real-world Reveal LINQ ICM study. Only studies using concomitant external Holter monitoring (typically feasible only over a short follow-up) can define the true sensitivity for AF detection.[19] Second, only short ECG segments (either 10 seconds or 2 minutes at the onset) were available to help adjudicate the AF episodes. Thus, it was necessary to assume that the ECG at onset represented the rhythm for the entire duration of the detected AF episode. Nonetheless, we were able to show a high degree of intraobserver and interobserver reproducibility for adjudication of ICM-detected events.

Conclusion

The episode detection performance of Reveal LINQ ICM is excellent in all patients for AF episodes lasting 1 hour or more. For shorter-duration episodes, the ICM's performance is dependent on the incidence rate of AF in the patient population being monitored. Furthermore, the programmed sensitivity of the AF detection algorithm optimizes the episode detection performance depending on the clinical relevance of AF diagnosis in the patient being monitored. Episode adjudication burden can be reduced significantly (with a small relative compromise or delay in diagnostic yield) by limiting storage to only the longest detected episode in clinical scenarios in which short-duration episodes are not clinically relevant. Our data have important implications for programming of the LINQ ICM, which may translate into more efficient follow-up of patients with these devices.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2016.05.010.

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